Amendments to the Claims:

1. (Currently amended) A method for making a silicon rubber balloon ~~catheters made of silicon rubber~~ catheter, the method comprising the steps of:

extruding an elongated lumen tube provided with a drainage lumen and an inflation lumen therein, wherein the elongated lumen tube has a diameter less than the silicon rubber balloon catheter;

vulcanizing the elongated lumen tube;

cutting the vulcanized, elongated lumen tube ~~into a plurality of~~ to form one or more unit length lumen tubes;

fitting a support rod in the drainage lumen of the unit length lumen tube;

forming ~~one or more~~ two apertures through the unit length lumen tube at ~~the~~ a balloon forming region, wherein the two apertures each have a diameter of approximately 0.5 mm;

coating an outer surface of the unit length lumen tube uniformly at the balloon forming region with a bond preventing agent while turning the unit length lumen tube along its circumference, wherein the coating of the bond preventing agent has straight edges;

removing the support rod from the unit length lumen tube;

connecting ~~a plurality of~~ the coated unit length lumen tube to another coated unit length lumen tube ~~tubes in series~~ with ~~one or more~~ a ~~connectors~~ connector to form a series of unit length lumen tubes;

extruding a balloon tube having uniform thickness ~~on~~ over the series of unit length lumen tubes such that the series of unit length lumen tubes is within the balloon tube;

ensuring that the bond preventing agent is not discolored or has not deteriorated;

vulcanizing the balloon tube;

cutting the balloon tube ~~into a plurality of~~ to form one or more unit length balloon tubes, wherein the unit length balloon tube is approximately equivalent in length to the unit length lumen tube;

removing the ~~one or more connectors~~ connector from the unit length ~~balloon tubes~~ lumen tube;

forming a tip at one end of the unit length balloon tube; and

forming a urine drainage hole through the unit length balloon tube and through the drainage lumen within the unit length lumen tube.

2. (Previously presented) The method of claim 1, wherein the drainage lumen has a greater diameter than of the inflation lumen.

3. (Cancelled) The method of claim 1, wherein two apertures are formed at the balloon forming region of the unit length lumen tube.

4. (Cancelled) The method of claim 3, wherein the diameter of the two apertures is approximately 0.5 mm.

5. (Previously presented) The method of claim 4, wherein the two apertures are spaced approximately 2 mm to 3 mm apart.

6. (Currently amended) The method of claim 1, wherein the ~~one or more~~ two apertures are formed through the unit length lumen tube adjacent to opposite edges of the balloon forming region.

7. (Previously presented) The method of claim 1, wherein the drainage hole is formed through the unit length balloon tube between the tip and the balloon forming region.

8. (Currently amended) The method of claim 1, wherein the support rod is fitted in the drainage lumen of the unit length lumen tube to extend up to ~~a~~ the balloon forming region.

REMARKS

The applicant has studied the Final Office Action dated September 23, 2003, and has made amendments to the claims. The applicant respectfully request entry of this amendment pursuant to 37 C.F.R. § 1.116 in that the amendment and remarks below place the application and claims in condition for allowance or, at least, present the application in better form for appeal. Upon entry of this amendment, claims 1-8 are pending. Claims 3 and 4 have been cancelled without prejudice, and claims 1, 6 and 8 have been amended. It is submitted that the application, as amended, is in condition for allowance. Reconsideration and reexamination are respectfully requested.

A substitute specification is enclosed herein to replace the original specification filed with the application. A marked up copy, which shows the changes made to the original specification, is also enclosed for the Examiner's convenience. The Examiner rejected the substitute specification filed in response to the Office Action dated March 27, 2003 for failing to comply with 37 C.F.R. § 1.125. The applicant has duly noted the examples provided of matter considered new by the Examiner. The applicant has amended the specification to conform with § 1.125(b) and (c) as well as to reflect proper idiomatic English. In particular, the substitute specification reflects amendments to the examples provided by the Examiner, as described above. It is believed that this amendment does not introduce new matter in the application. The substitute specification includes the same changes as are indicated in the marked-up copy of the original specification, showing additions and deletions.

Claims 1-8 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement due to the lack of the following recitations: "coating the mold lubricant only to a portion punched the balloon injection opening in the first tubing while turning the circumference of the outer surface of the first tube"; "forming the coating boundary surface as a straight line"; "the second tube having uniform thickness"; "ensuring the coating portion of the mold lubricate does not discolor or the characteristic of the mold lubricant does not deteriorate"; "an elongated lumen that has an outer diameter slight smaller than the diameter of the desired finished catheter"; and "forming apertures with a diameter of about 0.5 mm."

Applicant has amended claim 1 to include the aforementioned recitations in order to satisfy the enabling requirement. Accordingly, it is respectfully requested that this rejection under § 112, first paragraph be withdrawn.

Claims 1-8 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement due to the lack of support in the specification concerning the following: "forming one or more apertures" in claim 1; "forming a drainage hole" in claim 1; and "the one or more apertures" in claim 6. Claims 1 and 6 have been amended to clearly identify the present invention. In particular, claim 1 and 6 are amended to recite "two apertures." Also, claim 1 is amended to recite "a urine drainage hole." Accordingly, it respectfully requested that this rejection be withdrawn.

Claims 1-8 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, claim 1 has been amended to reflect proper antecedent basis with respect to "a balloon forming region." Also, claim 1 has been amended to clarify the steps concerning the connection of the unit length lumen tubes, the extrusion of the balloon tube over the series of the unit length lumen tubes, cutting the balloon tube, and forming the drainage hole. Also, claim 8 has been amended to refer the balloon forming region to the one recited in amended claim 1. Therefore, it respectfully requested that this rejection be withdrawn.

No amendment made was related to the statutory requirements of patentability unless expressly stated herein; and no amendment made was for the purpose of narrowing the scope of any claim, unless Applicant has argued herein that such amendment was made to distinguish over a particular reference or combination of references.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California, telephone number (213) 623-2221 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,
Lee, Hong, Degerman, Kang & Schmadeka

Date: December 23, 2003

By: Amit Sheth
Amit Sheth
Registration No. 50,176
Attorney(s) for Applicant(s)

Customer No. 035884
Lee, Hong, Degerman, Kang & Schmadeka
801 S. Figueroa Street, 14th Floor
Los Angeles, California 90017
Telephone: 213-623-2221
Facsimile: 213-623-2211

METHOD FOR ~~MACKING~~ MAKING BALLOON CATHETER

BACKGROUND OF THE INVENTION

~~1.~~ Field of the Invention

The present invention relates to a method for making a silicon balloon catheter, and more particularly to a method for making a silicon balloon catheter in which a ~~first tube having its outer diameter slightly smaller than that of a desired catheter is formed by an extruding method, mold lubricant is coated at a portion of a balloon injection opening, a thin film type second tube is formed at the coated outer surface of the first tube by a second extruding, and then the catheter is vulcanized and cut. As a result, when liquid is injected to an expansion tube, the second tube is separated from the first tube, thereby performing a function as a balloon~~ balloon is formed on a lumen tube having a fluid drainage lumen and an inflation lumen so that it is inflated when a liquid is injected into the balloon through the inflation lumen.

~~2.~~ Description of the Related Art

In general, a catheter made of silicon is a thin and long tube ~~being~~ adapted to be inserted into the human body in order to draw blood or to inject medicine. ~~For example, it is used a urine path tube, that is, it~~ Also, such a catheter may be used to drain urine. In this case, the catheter is inserted ~~to~~ into the bladder through the urethra ~~in order to make~~ so as to drain urine ~~filled with~~collected in the bladder ~~discharge.~~.

~~Figure~~ Fig. 1 is a ~~cross~~-sectional view illustrating a conventional balloon catheter ~~in accordance with a conventional art. Figure~~. Fig. 2 is a ~~block diagram~~flow chart illustrating a conventional method for manufacturing ~~method of a~~ the balloon catheter ~~in accordance with a~~

~~conventional art.~~.

~~In a construction of the conventional art (referring to Figure 1), a tube 13 has a partition 19 between a discharge tube path 12 for discharging urine through a urine discharge opening 17 and an expansion tube 14 for expanding a balloon. A balloon layer 16 is adhered to an outside of the tube 13 by an adhesive 18. Also, the conventional catheter has a balloon injection opening 15 for making the expansion tube 14 and the inside 16a of the balloon communicate.~~

~~In order to manufacture the catheter as constructed above, firstly, the tube 13 is extruded in order to provide the discharge tube path 12 and an expansion tube 14 in step S1, thereafter vulcanized in step S2 and cut with a predetermined length in step S3.~~

~~Next, the balloon injection opening 15 and the urine discharge opening 17 are punched in step S4 and then a tip portion 11 is formed in step S5. Thereafter, the balloon 16 molded~~ As shown in Fig. 1, the conventional balloon catheter includes a lumen tube 13 formed with a partition 19 therein to define a primary lumen 12 and an inflation lumen 14, and a balloon layer 16 partially bonded to an outer surface of the lumen tube 13 to provide a balloon. The primary lumen 12 serves to drain urine introduced from the bladder through a urine drainage hole 17, whereas the inflation lumen 14 serves to inflate the balloon provided by the balloon layer 16. An inflation hole 15 is also formed at the lumen tube 13 in order to communicate the inflation lumen 14 with the interior of the balloon.

In order to manufacture the balloon catheter having the above mentioned configuration, an extrusion process is carried out to extrude an intermediate tube having the primary lumen 12 and inflation lumen 14 (Step S1), as shown in Fig. 2. Thereafter, the extruded intermediate tube is vulcanized (Step S2), and then cut into tube pieces having a desired length, that is, lumen tubes 13 (Step S3).

Subsequently, the inflation hole 15 and urine drainage hole 17 are perforated through each lumen tube 13 (Step S4). A tip 11 is then formed at one end of each lumen tube 13 (Step S5).

Thereafter, a balloon manufactured in a separate molding process~~, i.e., the step~~ (Step S6~~,~~) is ~~adhered~~bonded, as the balloon layer 16, to the outer surface of each lumen tube 13 by an adhesive ~~in step~~(Step S7~~ and then over-coated in step S8.~~). Each lumen tube 13 is then subjected to an overcoating process (Step S8) to complete the balloon catheter having the configuration of Fig. 1.

~~However, in the catheter as described above, there are several disadvantages that since it is manufactured by an adhesion of a balloon molded by a separate process, the diameter of the balloon portion become thicker relatively in comparison with an another portion of the catheter. As a result, the portion caused a patient to feel a very big pain in the surgical operation and also sometimes there is a serious situation that the adhesive portion is apt to be separated.~~

~~Also,~~ In the above mentioned conventional balloon catheter, however, there is a problem in that it may cause a patient great pain during a surgical operation because its balloon-bonded portion has a diameter relatively larger than that of other portions. Furthermore, the bonded portions of the balloon may be separated.

Another conventional catheter manufacturing method is disclosed in U.S. Patent~~:~~ No. 5,137,671~~ disclose an another conventional catheter manufacturing method.~~.

~~In the explanation of the manufacturing~~ This method will be described hereinafter with reference to ~~drawings, as shown in Figure~~Figs. 3a~~, there is provided a tube 100.~~ to 3g. First, a double lumen tube 100 is prepared, as shown in Fig. 3a. The double lumen tube 100 ~~includes a~~ is formed with a first ~~tube~~lumen 120 (a ~~tube having a big diameter~~larger fluid conduit lumen) and a second ~~tube~~lumen 140 (a smaller capillary ~~tube having a small diameter~~lumen).

~~When the tube 100 as described above is provided, as shown in Figure 3b, a first opening 160 communicating the second tube 140 at the outer surface of the balloon expansion unit is punched. Thereafter, a polymerization type filling material 180 like silicon rubber is filled within the second tube 140 from an end (a lower end) of the tube 100 to the first opening 160. Also, a~~ A capillary lumen

access opening 160 is punched through at an intermediate portion of the prepared lumen tube 100, that is, a balloon inflating portion, so that it communicates with the second lumen 140, as shown in Fig. 3b. The second lumen 140 is then filled with a polymeric fill material 180 such as silicon rubber between one end thereof (that is, the left end in Fig. 3b) and a point just before the capillary lumen access opening 160. A tip 200 is attached to ~~a lower~~one end of the lumen tube 100 corresponding to the one end of the ~~tube 100 and then the ends~~second lumen 140, so that both of the first and second ~~tubes~~lumens 120 and 140 are closed~~.~~ at one end thereof.

~~Next,~~ Subsequently, a portion of the lumen tube 100 extending from one end of the lumen tube 100 to the balloon inflating portion, that is, up to the line A - A in Fig. 3c, is dipped into ~~mold lubricant~~ a bond preventing agent solution (a liquid ~~(soapy water~~soap or ~~Vaseline liquid etc.) from its end to the balloon expansion unit, especially until the line of A-A of the tube 100 and then~~ petrolatum), and then dried, so that it is coated with a solidified~~. Thereafter, the tube 100 is coated by a mold lubricant~~ bond preventing agent layer 300~~ until~~. The bond preventing agent layer 300 fills the ~~balloon expansion unit of the outer surface of the tube. At the same time, the mold lubricant 300 is filled at the first~~capillary lumen access opening 160 and a portion of the second ~~tube~~ lumen 140~~, so that~~. Thus, the ~~tube is formed~~bond preventing agent layer 300 has a cross section as shown in Figure. 3c. ~~That is, the mold lubricant is filled within the second tube from the line of A-A of the balloon expansion unit to the first opening and coated at the outer surface of the tube between the lines of A-A and B-B.~~ That is, the portion of the second lumen 140 between the line A - A and the capillary lumen access opening 160 is filled with the bond preventing agent layer 300, whereas the outer surface portion of the lumen tube 100 between the line A - A and the end of the lumen tube 100 adjacent to the tip 200 is coated with the bond preventing agent layer 300, along with the tip 200.

~~Thereafter, as shown in Figure 3d, the tube 100 is processed by surface active agent until before (the line of B-B) the balloon expansion unit, dipped into predetermined water or hot water on~~

~~several times and then the mold lubricant coated except for the balloon expansion unit is removed. Thereafter, as shown in Figure 3e, many folds layers, that is two folds in the Figure 3e, are coated at the entire outer surface of the tube 100, thereby forming an overcoat layer 400.~~

~~Next, the filled and coated mold lubricant of the balloon expansion unit is removed through the second tube 140 of the tube, thereby forming a space portion 440 for expanding the balloon.~~

~~However, in case of the balloon catheter manufactured by the above processes, after dipping the tube into the mold lubricant liquid, the mold lubricant coated at a portion (between the end and the line of B-B) except for the balloon expansion opening is removed. At this time, in the dipping process of the tube in water by several times, wastewater is increased, thereby occurring environmental pollution.~~

~~Also, there is a disadvantage that when the mold lubricant did not completely removed, after forming the space portion, pushing phenomenon is occurred, so that the surrounding overcoat layer is exfoliated and swelled together with the space portion.~~

~~Also, the conventional catheter manufacturing method does not solve the problem that the diameter of the balloon portion is thicker than that of the other portion.~~

~~As an example of an another conventional art, a silicon rubber catheter is disclosed in Japanese Patent Registration No. 3015310 registered on June 21, 1995.~~

~~According to the above conventional art, a balloon is installed as one body in order to coat the surface of the catheter body. A catheter body having a discharge tube path formed by an extruding process through silicon rubber material and a drain at the outside of the tube wall is vulcanized and then mold lubricant is coated to a molding end (a portion for forming a balloon) of an insertion fixing portion. Thereafter, a wall (a balloon) is stacked at~~ Thereafter, a portion of the lumen tube 100 extending up to the line B - B in Fig. 3c, that is, just before the balloon inflating portion, is treated using a surface active agent, and then dipped into hot water or other hot aqueous solution several times, so as

to remove the bond preventing agent layer 300 therefrom. Thus, the bond preventing agent layer 300 remains only at the balloon inflating portion of the lumen tube 100, as shown in Fig. 3d. An overcoat layer 400 is then coated over the entire outer surface of the lumen tube 100, as shown in Fig. 3e. The overcoat layer 400 may have a multi-layer structure including laminated layers 410 and 420.

The remaining bond preventing agent layer 300 filling and covering the balloon inflating portion is completely removed through the second lumen 140 of the lumen tube 100, thereby forming a balloon cavity 440, as shown in Fig. 3f. Thus, a balloon catheter is obtained.

Referring to Fig. 3g, it can be seen that the conventional lumen tube 20 has a cross-sectional shape where its thickness ta and thickness Ta are relatively large. Typically, the conventional lumen tube 13 has a minimum thickness between the outer surface thereof and the surface of the inflation lumen 14, that is, ta, corresponding to 0.5mm, while having a minimum thickness between the outer surface thereof and the surface of the fluid drainage lumen 12, that is, Ta, corresponding to 0.9mm. Accordingly, workability in a subsequent operation for perforating inflation apertures while allowing the fluid drainage lumen to have a size as large as possible is significantly reduced.

This balloon catheter manufacturing method has a problem in that it causes environmental pollution due to waste water produced during the procedure of dipping the lumen tube 100 into water several times in order to remove the bond preventing agent from the portion of the lumen tube 100 (between the line B - B and the tip-side end) other than the balloon inflating portion.

Additionally, where the bond preventing agent is incompletely removed, the residue thereof is moved to the peripheral edge of the balloon cavity formed at the balloon inflating portion when the balloon cavity is inflated, thereby causing the overcoat layer to be stripped around the balloon inflating portion. As a result, the overcoat layer may be inflated around the balloon inflating portion.

Also, the above mentioned conventional balloon catheter manufacturing method still has the problem caused by the diameter of the balloon inflating portion being larger than that of other portions.

As another conventional example, there is a silicon rubber catheter disclosed in Japanese Patent No. 3015310 registered on June 21, 1995.

In this catheter, a balloon is formed on the outer surface of a catheter body such that it is integral with the catheter body. The catheter body is formed using silicon rubber in accordance with a primary extrusion process so that it is defined with a fluid conduit lumen and a capillary lumen therein, and formed with a channel at the outer surface thereof. The catheter body is subjected to a vulcanization process, and then coated with a bond preventing agent at a balloon forming portion thereof. Thereafter, a balloon layer is laminated using silicon rubber over the outer surface of the catheter body in accordance with a secondary extrusion process, and then vulcanized. A tip is then formed at the catheter body. In this structure, the outer surface of the ~~tube wall~~balloon layer is flush with the outer surface of the catheter body ~~and vulcanized again and so a tip portion is formed. At this time, the wall and the tube wall of the catheter is formed at the same surface~~at the catheter body portion other than the balloon forming portion, so that ~~the resistance by the~~there is no step ~~portion of the wall surface is broken off and at the same time, transformation of the wall surface is prevented.~~formed at the outer surface of the catheter body. Accordingly, there is no resistance caused by steps.

~~However, practically, it is impossible to manufacture the expansion tube of a continuous drain type for expanding/contracting the balloon according to the above conventional art.~~

~~Because~~ However, it is difficult to practically manufacture such a catheter, in which the balloon is integral with the catheter body.

This is because the silicon rubber layer coated in ~~second extruding makes~~the secondary extrusion process may penetrate into the ~~drain to be depressed. If the silicon rubber layer is coated with thinness, since the adhesion force is not sufficient, a phenomenon that a portion except for the balloon portion is exfoliated is occurred.~~channel. Where the silicon rubber layer is coated without any penetration thereof into the channel, it is difficult to obtain a sufficient bonding force to the catheter body.

In this case, the silicon rubber layer may be stripped even at a region other than the balloon forming portion.

SUMMARY OF THE INVENTION

~~To solve the above problems, it is an object of the present invention to provide a method for making a silicon balloon catheter in which since a step portion of the balloon portion is removed, a pain to the patient in surgical operation is relieved. Also, a portion except for the balloon portion is prevented from separating, at the same time productivity can be enhanced and the manufacturing cost can be reduced.~~

~~To achieve the above object, there is provided a method for making a balloon catheter using silicon rubber A method for making a balloon catheter using silicon rubber comprising the steps of: forming a first tube by extruding firstly, the tube having its outer diameter slightly smaller than that of a desired catheter, then vulcanizing and cutting the first tube; punching two balloon injection openings having small diameter at a portion for expanding into balloon in the first tube after inserting a support rod into a discharge tube path; coating mold lubricant at a portion of the balloon injection opening; connecting the first tubes coated the mold lubricant by using a connection unit after removing the support rod, and thereafter forming a second tube at the coated outside surface of the first tube by extruding secondly, performing a vulcanizing process and cutting again; forming a tip at the tip portion of the first and second tubes; and punching a urine discharge opening at the first tube.~~

~~An embodiment of the present invention is disclosed in order to make a silicon rubber catheter having no a step portion economically, in which when air is injected to an expansion tube, a portion coated by mold lubricant between the first and second tubes is separated and expanded, thereby performing a function as a balloon.~~ Accordingly, the present invention is directed to a silicon rubber

balloon catheter that solves the above problems.

An object of the present invention is to not require a step at a balloon portion thereof, thereby being capable of alleviating pain caused to a patient during a surgical operation while preventing a balloon layer from being separated from a region other than the balloon portion

It is another object of the present invention to achieve an improvement in productivity and a reduction in manufacturing costs.

Additional features and advantages of the invention will be set forth in the description which follows, and in part will be apparent from the description, or may be learned by practice of the invention. The objectives and other advantages of the invention will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

To achieve these and other advantages and in accordance with the purpose of the present invention, as embodied and broadly described, a method for making balloon catheters made of silicon rubber, comprises the steps of: extruding an elongated lumen tube provided with a drainage lumen and an inflation lumen therein; vulcanizing the elongated lumen tube; cutting the elongated lumen tube into unit length lumen tubes; fitting a support rod in the drainage lumen of the unit length lumen tube to extend up to a balloon forming region; forming one or more apertures through the unit length lumen tube at the balloon forming region; coating an outer surface of the unit length lumen tube at the balloon forming region with a bond preventing agent; removing the support rod from the unit length lumen tube; connecting a plurality of unit length lumen tubes in series with one or more connectors; extruding a balloon tube on the series of unit length lumen tubes; vulcanizing the balloon tube; cutting the balloon tube into unit length balloon tubes; forming a tip at one end of the unit length balloon tube; and forming a drainage hole through the unit length balloon tube.

According to one aspect of the preferred embodiment, the drainage lumen has a greater diameter

than of the inflation lumen.

According to another aspect of the preferred embodiment, there are preferably two apertures, with a diameter of approximately 0.5mm and are spaced approximately 2mm – 3mm apart, and are formed at the balloon forming region of the unit length lumen tube. More particularly, the two apertures are formed through the unit length lumen tube adjacent to opposite edges of the balloon forming region.

According to another aspect of the preferred embodiment, the drainage hole is formed through the unit length balloon tube between the tip and the balloon forming region.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide a further explanation of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

The above objects, and other features and advantages of the present invention will become more apparent ~~from~~ after a reading of the following detailed description when taken in conjunction with the ~~accompanying~~ drawings, in which:

Fig. 1 is a sectional view illustrating a ~~construction of~~ conventional balloon catheter ~~in accordance with the conventional art;~~;

Fig. 2 is a ~~block diagram~~flow chart illustrating a ~~method for making a balloon catheter in accordance with the~~ conventional ~~art;~~method for manufacturing the balloon catheter;

Figs. 3a to ~~3f~~ 3g are ~~longitudinal cross~~-sectional views respectively illustrating ~~processes~~sequential steps of a conventional method for manufacturing a balloon catheter ~~manufacturing method in accordance with the conventional art;~~;

Figs. 4a to ~~4i~~ 4h are ~~longitudinal cross~~-sectional views respectively illustrating

~~processes~~sequential steps of a ~~balloon catheter manufacturing method in accordance with the~~ method for making a balloon catheter according to an embodiment of the present invention;

Fig. 5 is a ~~cross~~-sectional view illustrating ~~a construction of a~~ the configuration of the balloon catheter manufactured in accordance with the method of the present invention; and

Fig. 6 is a ~~block diagram~~flow chart illustrating ~~a method for making a~~the balloon catheter ~~in accordance with~~manufacturing method of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Preferred embodiments of the present invention will now be described in detail, with reference to Figs. 4a to 4~~i~~6.

Figs. 4a to 4h are ~~longitudinal cross~~-sectional views respectively illustrating ~~processes of a balloon catheter manufacturing method in accordance with the present invention. Fig. 5 is a cross-sectional view illustrating the construction~~sequential steps of a ~~balloon catheter manufactured in accordance with the present invention. Fig. 6 is a block diagram illustrating a~~ method for making a balloon catheter ~~in accordance with the present invention.~~

~~Firstly, as shown in Fig. 4a, in a preferred embodiment of the present invention, a first tube is formed by~~ according to an ~~extruding method. The outer diameter of the first tube is slightly smaller than the diameter of a desired balloon catheter. The first tube 20 provides with a discharge tube path 22 and an expansion tube 24 (step of S11 of Fig. 6). Thereafter, the first tube is vulcanized and as a result it has elasticity and thereafter, it is cut with a predetermined length in the step of S12.~~embodiment of the present invention. Fig. 5 is a sectional view illustrating the configuration of the balloon catheter manufactured in accordance with the method of the present invention. Fig. 6 is a flow chart illustrating the balloon catheter manufacturing method of the present invention.

~~At this time, the cross-section of the first tube 20 has the form like Fig. 4c. Fig.~~ In accordance

with the illustrated preferred embodiment of the present invention, as shown in Fig. 4a, a lumen tube 20 is extruded in accordance with a primary extrusion process (Step S11 in Fig. 6). The lumen tube 20 is formed with a fluid drainage lumen 22 and an inflation lumen 24 while having an outer diameter slightly smaller than the outer diameter of a desired balloon catheter to be finally obtained. The extruded lumen tube 20 is then subjected to a vulcanization process so that it has a desired elasticity. In order to manufacture such a lumen tube in a continuous manner, an elongated lumen tube is practically extruded, which is, in turn, cut into a plurality of unit lumen tubes each corresponding to the lumen tube 20 (Step S12 in Fig. 6).

The lumen tube 20 has a cross-sectional shape shown in Fig. 4b ~~shows a cross-section shape of the conventional art.~~ Thickness tb and thickness Tb, which are relatively small, illustrate an enhanced workability in a subsequent operation for perforating inflation apertures while making the fluid drainage lumen have a size as large as possible. This will be described in detail hereinafter.

~~As shown in the above drawings, the form of the cross-section of the tube 13 of the conventional art is slightly similar to that of the first tube 20 of the present invention. However, the thickness, tb and Tb, of the first tube 20 are significantly thinner than that, ta and Ta of the conventional tube 13. This is for securing facilities in working when punching the balloon injection opening to be explained hereinafter, enhancing the rate of success, and securing a urination discharge tube path as large as it can.~~

~~Also, at the outside of the first tube 20 can form thinly as shown in Fig. 4c, considering the coated thickness again in second extruding process. In general, the thickness ta between the outside surface of the conventional tube 13 and the expansion tube 14 is 0.5mm and the thickness Ta of circumference is 0.9mm. Whereas, it is desirous that the thickness tb between the outside surface of the first tube 20 of the present invention and the expansion tube 24 is 0.3mm and the thickness Tb of circumference of the first tube 20 is 0.7mm.~~

~~Also, a horizontal type extruding machine and a vulcanizing machine are used in the conventional tube extruding S1 and vulcanization S2 processes. Whereas, it is desirous that a vertical type extruding machine and a vulcanizing machine are used in the first tube extruding S11 and vulcanization S12 processes. When the horizontal type extruding machine and the vulcanizing machine are used, some contact traces are remained to the surface of the tube, so that the traces are remained as scars at the balloon portion in next time, thereby generating eccentricity in balloon expansion or breaking the balloon.~~

~~Next, as shown in Fig. 4d, a balloon injection opening 23 is punched to the first tube 20 in step 13. At this time, a support rod 29 (referring to Fig. 4e) is inserted to the discharge tube path 22, so that the rubber tube is maintained in straight line, thereby capable of performing work easily. When forming the balloon injection opening 23, in the conventional art, an opening having a big diameter (about the diameter of 1.5mm) is punched at the center portion (15 of Fig. 1). Whereas, in an embodiment of the present invention, two openings (about the diameter of 0.5mm) are punched at an edge portion of the balloon formation portion, that is, apart from about 2~3mm from the boundary line. The two openings are as small as it can and smaller than that of the opening of the convention art.~~

~~Here, the opening of the balloon injection opening 23 is formed in small, because, if the opening is big, the balloon formation layer 30' is depressed into the opening in the second extruding process (S16 of Fig. 6) and the thickness of the balloon become to be differed. As a result, when expanding the balloon, it does not expand symmetrically and it may become a cause of breaking.~~

~~Next, as shown in Fig. 4f, mold lubricant 28 is coated to an outside portion, that is, a portion for forming the balloon, of the first tube 20 in step S14. In the mold lubricant coating process, since the mold lubricant must be coated only to the portion punched the balloon injection opening 23 in the first tube 20, turning the circumference of the outer surface of the first tube 20 by a round. Also, the coating boundary surface must be formed as a straight line, so it must take note of the work.~~

~~At this time, the used mold lubricant 28 is liquid type soap capable of purchasing easily in the street. Also, the mold lubricant 28 is used material by mixing Teflon liquid with transparent ink and it is desirous to add water or alcohol for fitting the viscosity.~~

~~As described above, the mold lubricant having the fitted viscosity is deposited in a sponge etc. and then coated only to the portion punched the balloon injection opening 23, turning the first tube by a round uniformly. After coating the mold lubricant, it is exposed to hot wind in weak with about 60~70°C in step S14.~~

~~After the mold lubricant is dried sufficiently, the support rod 29 inserted to the injection tube path is removed (referring to Fig. 4f). Thereafter, the first tubes are connected with the same direction by a connecting unit 39 (referring to Fig. 4g) lengthwise in step S15, so that when extruding the second tube, a continuous working is possible.~~

~~Next, as shown in Fig. 4h, a second tube 30 is formed at the outside of the first tube 20 through the second extruding process by using a vertical type extruder in step S16 and then vulcanized by using a vulcanizing machine in step S17. At this time, the thickness of the second tube must be maintained uniformly and also it is required that the coating portion of the mold lubricant does not discolor or the characteristic of the mold lubricant does not deteriorate.~~

~~In the tube completed the vulcanizing process, the portion connected before the second extruding is cut again in step S17 and then the connection units 39 are removed, a tip 40 is formed in step S18, as shown in Fig. 4I, and then a urine discharge opening 26 is punched.~~

~~The product completed through the above processes is shown in Fig. 5, the balloon formation portion 30' is expanded symmetrically with each other when air is injected through the expansion tube 24, so that an expansion tube 32 is formed.~~

~~On the other hand, in the conventional balloon manufacturing processes, a worker is required in the processes S1~S4 of tube extruding, vulcanizing, cutting and punching in the balloon injection~~

~~opening/a urine discharge opening, respectively. Five and three workers are required in the tip formation process in step S5 and balloon molding process in step S6, respectively. Also, eight and five workers are required in the balloon adhesion process in step S7 and overcoat process in step S8, respectively. As a result, many workers are required and so it caused the manufacturing cost to rise.~~

~~Whereas, in manufacturing the balloon catheter of the present invention, nine workers all are sufficient. That is, a worker is required in the first tube extruding and vulcanizing/cutting processes S11 and S12. Two workers are required in the punching process of the support rod insertion and the balloon injection opening S13. A worker is required in the coating process S14 of mold lubricant. Two workers are required in the process S15 of the support rod removal and the first tube connection. A worker is required in the processes of the second tube extruding S16 and the vulcanizing/cutting S17. A worker is required in the processes S 18 and S19 of tip formation and punching a urine discharge opening, respectively. Therefore, according to the present invention, there are several advantages that the workers and the cost are reduced.~~

~~According to the embodiment of the present invention as described above, there is provided to a method for making a silicon balloon catheter in which a first tube having its outer diameter slightly smaller than that of a desired catheter is formed by an extruding method, mold lubricant is coated at a portion of a balloon injection opening, a thin film type second tube is formed at the coated outer surface of the first tube by a second extruding, and then the catheter is vulcanized and cut. As a result, when liquid is injected to an expansion tube, the second tube is separated from the first tube, thereby performing a function as a balloon. Also, since a step portion of the balloon portion is removed, a pain to the patient in surgical operation is relieved. A portion except for the balloon portion is prevented from separating, at the same time productivity can be enhanced and the manufacturing cost can be reduced.~~

~~While the invention has been shown and described with reference to certain preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and~~

~~details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.~~ Taking into consideration the thickness of an overcoat layer to be formed on the lumen tube 20 in a secondary extrusion process, the lumen tube 20 can have a reduced thickness, as described above and shown in Fig. 4b. The lumen tube 20 may have a minimum thickness between the outer surface thereof and the surface of the inflation lumen 24, that is, tb, corresponding to 0.3mm, while having a minimum thickness between the outer surface thereof and the surface of the fluid drainage lumen 22, that is, Ta, corresponding to 0.7mm.

In the method of the present invention, it is desirable to use a vertical extruder and a vertical vulcanizer in the primary extrusion process (Step S11) and the vulcanization process (Step S12) in the method of the present invention, respectively. Where the horizontal extruder and vulcanizer are used, contact traces are formed. Even if these contact traces are fine, they remain in the form of defects at a region where a balloon is formed. The defects cause an eccentric inflation of the balloon or rupture of the balloon upon the inflation.

Thereafter, inflation apertures 23 are perforated through the lumen tube 20, as shown in Fig. 4c (Step S13). The perforating process can be conveniently carried out by inserting a support rod 29 into the fluid drainage lumen 22, thereby maintaining the lumen tube 20 in a straight state, as shown in Fig. 4d. Two inflation apertures 23 having a diameter (about 0.5mm) smaller than that of the conventional inflation hole are formed at positions adjacent to opposite edges of the balloon region while being spaced apart from the opposite edges by a distance of about 2 to 3mm, respectively.

Should the inflation apertures 23 be excessively large, a balloon layer subsequently coated to form a balloon in a secondary extrusion process (Step S16 in Fig. 6) may penetrate into the inflation apertures 23, thereby causing the balloon to have a non-uniform thickness. As a result, the balloon may be ruptured upon its inflation.

Thereafter, a bonding preventing agent 28 must coated on the outer surface of the lumen tube

20 at a region only where the inflation apertures 23 are formed, as shown in Fig. 4e (Step S14). In this coating process, care should be taken because the bonding preventing agent 28 must be uniformly and completely coated around the outer surface of the lumen tube 20 at the balloon forming region, where the inflation apertures 23 are formed, such that its edges extend straight.

For the bonding preventing agent 28, a commercially available liquid soap or a mixture of an aqueous transparent ink with a Teflon solution may be used. In order to obtain a desired viscosity, the bonding preventing agent 28 may be added with water or alcohol.

The coating process is carried out by wetting a sponge with the bonding preventing agent 28 having an appropriate viscosity obtained in the above described manner, bringing the sponge into contact with a portion of the lumen tube 20 corresponding to the balloon forming region, and rotating the lumen tube 20 one turn in a state of being in contact with the sponge. Thus, the bonding preventing agent 28 can be uniformly coated over the lumen tube portion corresponding to the balloon forming region. The coated bonding preventing agent 28 is then dried by warm air of about 60 to 70°C gently blown thereto (Step S14).

After the bonding preventing agent 28 is sufficiently dried, the support rod 29 is removed from the fluid drainage lumen 22 of the lumen tube 20 (Fig. 4e). As shown in Fig. 4f, the lumen tube 20 is then fitted around one end of a connector 39 so that it is connected with another lumen tube 20 fitted around the other end of the connector 39. In such a manner, a plurality of lumen tubes 20 are connected in series by a plurality of connectors 39 (Step S15), so that a continuous secondary extrusion process can be carried out for the lumen tubes 20.

A thin silicon rubber tube is then extruded in accordance with the secondary extrusion process while passing the connected lumen tubes 20 through a vertical extruder and a vertical vulcanizer (Step S16), and then vulcanized (Step S17), so that a balloon tube 30 is coated over each lumen tube 20, as shown in Fig. 4g. The secondary extrusion process should be carefully carried out in order to obtain a

uniform thickness of the balloon tube 30, which must be maintained, and to prevent discoloration and degradation in removability at the region where the bond preventing agent is coated.

The vulcanized tube product is then cut into tube pieces respectively corresponding to the connected lumen tubes 20 at step S17. Subsequently, the connectors 39 are separated from the tube pieces, thereby separating the tube pieces. A tip 40 is then formed at one end of each tube piece, as shown in Fig. 4h (Step S18). Finally, a urine drainage hole 26 is perforated through each tube piece. Thus, balloon catheters are completely manufactured.

A balloon catheter manufactured in accordance with the above described procedures is shown in Fig. 5. In Fig. 5, the reference numeral 30' is a balloon portion of the balloon catheter provided by the balloon tube 30. When a liquid is injected into the balloon catheter through the inflation lumen 24, the balloon portion of the balloon catheter is symmetrically inflated.

In accordance with the present invention, it is possible to achieve a reduction in labor, and thus, a reduction in manufacturing costs because the manufacturing processes can be easily carried out, and the number of manufacturing processes is reduced.

As apparent from the above description, the present invention provides a method for making a balloon catheter having no step at its outer surface by primarily extruding a lumen tube having an outer diameter slightly smaller than that of a balloon catheter to be finally manufactured, and coating a bond preventing agent on a portion of the lumen tube where a balloon is to be formed, and secondarily extruding a thin balloon tube on the lumen tube. When a liquid is injected into the balloon catheter through an inflation lumen provided at the lumen tube, the balloon tube is inflated while being separated from the lumen tube at a region where the bond preventing agent is coated, so that it serves as a balloon. Since the balloon catheter has a uniform outer diameter without having any step at the outer surface thereof, it is possible to reduce the pain caused to a patient during a surgical operation. It is also possible to achieve a reduction in manufacturing costs through an increase in productivity while

considerably reducing problems involved with the conventional cases, for example, separation of the balloon layer at a region other than the balloon region.